OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

COLD FILTERABLE VEGETABLE PEPTONE BROTH VG0104

COLD FILTERABLE VEGETABLE PEPTONE BROTH **VG0104**

Typical Formula*

	grams per litre
Vegetable peptone	18.0
Yeast extract	3.0
Sodium chloride	5.0
Di-potassium hydrogen phosphate	2.5
Glucose	2.5

* adjusted as required to meet performance standards

Directions

This product is not suitable for use as a product placebo in dry powder fill trials. This product has received a dose of Gamma-irradiation at 30 – 70 kGy. To prepare the medium add 31g to 1 litre of distilled water. Mix well to dissolve completely. Sterilize by filtration.

Physical Characteristics

Straw, free-flowing powder
Colour on reconstitution - straw 3-4
Moisture level - less than or equal to 7%
pH - 7.1 ± 0.2 at 25°C
Clarity - clear
Vcap - Polyvinylidene fluoride - equal to or greater than 500ml/47mm disc
(equivalent to or greater than 357 litres/m²)
Vcap - Polyethersulfone / Nylon - equal to or greater than 600ml/47mm disc
(equivalent to or greater than 429 litres/m²)

Sterility of powder (post irradiation) - no evidence of microbial growth after incubation in Tryptone Soya Broth (CM0129) and Fluid Thioglycollate Medium (CM0173) for 14 days at 20-25°C and 30-35°C.

Microbiological Tests Using Optimum Inoculum Dilution

Control Media: Tryptone Soya Agar, Columbia Blood Agar Base enriched with 5% v/v horse blood or Sabouraud Dextrose Agar, where appropriate

Medium is challenged with 10-100 colony-forming units

Reactions after incubation at 30-35°C for 24 hours

Escherichia coli	ATCC®8739	Turbid growth
Staphylococcus aureus	ATCC®6538	Turbid growth

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Pseudomonas aeruginosa	ATCC®9027	Turbid growth
Salmonella abony	NCTC6017	Turbid growth
Salmonella typhimurium	ATCC®14028	Turbid growth

Reactions after incubation at 20-25°C for 48 hours

Bacillus subtilis	ATCC®6633	Flocculent/surface growth
Candida albicans	ATCC®10231	Flocculent/surface growth

Reactions after incubation at 20-25°C for 72 hours

Kocuria rhizophila	ATCC®9341	Turbid growth

Reactions after incubation at 20-25°C for 5 days

Aspergillus brasiliensis	ATCC®16404	White mycelia, black spores/no spores

A satisfactory result is represented by visible growth.

The Microbiological Quality Control of this product complies with the following current pharmacopoeia;
British Pharmacopoeia
European Pharmacopoeia
The Japanese Pharmacopoeia
The United States Pharmacopoeia

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Revision History

Section / Step	Description of Change	Reason for Change	Reference
Entire Document	Update to new document format and correction of typographical/minor errors.	N/A	N/A